

Attorney Docket No.: DEX-0312
Inventors: Salceda et al.
Serial No.: 10/078,090
Filing Date: February 14, 2002
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REMARKS

Claims 1-17 are pending in the instant application. Claims 6 and 10-17 have been withdrawn from consideration and subsequently canceled without prejudice by Applicants in this amendment. Claim 1-5 and 7-9 have been rejected. Claim 1 has been amended. New claims 18 through 21 have been added. Support for these amendments is provided in the specification at pages 13-15, page 20, lines 8-11, and page 32, lines 1-20. Thus, now new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed January 28, 2004. Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice nonelected claims 6 and 10-17. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

With respect to the Examiner's denial of Applicants' request to include SEQ ID NO:47 because no common core structure is disclosed for SEQ ID NO:47 and 48, Applicants are providing

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herewith a sequence alignment of SEQ ID NO:47 and 48 clearly demonstrating the core structure which these sequence share. Reconsideration of inclusion of SEQ ID NO:47 within the instant claims is therefore respectfully requested.

II. Priority to Provisional Application

Applicants are providing herewith evidence, as requested by the Examiner, in the form of a sequence alignment demonstrating that SEQ ID NO:40 of U.S. Provisional Application Serial No. 60/268,999 is identical to SEQ ID NO:47 of the instant application. Further, evidence is provided herewith in the form of a sequence alignment demonstrating the core sequence shared by SEQ ID NO:47 and SEQ ID NO:48 of the instant invention. The provided evidence clearly demonstrates that the elected invention was disclosed in U.S. Provisional Application Serial No. 60/268,999 and that the priority claim is valid.

III. Objection to Claims

Claims 1-5 and 7-9 are objected to because they do not reflect the elected subject matter, namely SEQ ID NO:48 encoding polypeptide SEQ ID NO: 151.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to the elected sequences.

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Withdrawal of this objection is therefore respectfully requested.

IV. Rejection of Claims 1-5 and 7-9 under 35 U.S.C. 101 and 112

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. 101 and 112 as the Examiner suggests that the claimed invention lacks patentable utility.

Applicants respectfully traverse these rejections.

Data from bioassays demonstrating the utility of the claimed nucleic acid sequences is set forth in the specification at pages 111 through 118. As shown therein, using the Psmam001.dc bioassay, the claimed nucleic acid sequences were identified as differentially expressed in breast ductal cancer as compared to other normal tissues. Further, using the Psmam005.dc bioassay, the claimed nucleic acid sequences were identified as differentially expressed in breast ductal cancer as compared to other gynecological cancers.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980).

Clearly identification of SEQ ID NO:48 and 47 as being

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differentially expressed in breast cancer tissue as compared to normal tissue and other gynecological cancers constitutes a pharmacological activity relevant to the asserted use as a diagnostic for breast cancer, thus satisfying the utility requirement with respect to these nucleic acid molecules.

Withdrawal of these rejections under 35 U.S.C. § 101 and §112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1-5 and 7-9 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner suggests that the exact sequence of SEQ ID NO:48 meets the written description requirements. However, the Examiner suggests that the claims encompass gene sequences, encoding sequences and so forth which do not meet the written description provision of 35 U.S.C. § 112, first paragraph. Further, the Examiner suggests that there is insufficient description in the specification for nucleotides having more than 60% identity.

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Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that claim 1 has been amended and part (d) relating to nucleic acid molecules with at least 60% identity has been deleted, thus mooting this aspect of the rejection.

Further, in addition to the teachings of the specification acknowledged by the Examiner to meet the written description requirements for SEQ ID NO:48, Applicants respectfully direct the Examiner to page 111-118 wherein ATCC deposit information for clones containing this sequence are described. In accordance with MPEP § 2163, reference to a deposit may also satisfy the written description requirement with respect to a claimed material. Deposit of this clone clearly demonstrates Applicants' possession of other elements included in DNA and places the public in possession as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

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VI. Rejection of Claim 1-5 and 7-9 under 35 U.S.C. 112, first paragraph - Lack of Enablement

Claims 1-5 and 7-9 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner has acknowledged the specification to be enabled for the nucleic acid sequence of SEQ ID NO:48 but does not provide enablement for polynucleotides having at least 60% identity to polynucleotides encoding SEQ ID NO:151.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner citation of Skolnick et al. as being relevant to the instant claimed invention. Teachings of Skolnick et al. relate to a protein, not nucleic acid molecules as set forth in the instant claims.

Further, as discussed in Section V, Applicants have deleted part (d) of claim 1 relating to nucleic acid molecules with at least 60% identity, thus mooting this rejection.

Withdrawal of this rejection is therefore respectfully requested.

VII. Rejection of Claims 1-5 under 35 U.S.C. 102(a)

Claims 1-5 have been rejected under 35 U.S.C. 102(a) as

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being anticipated by the sequence of Accession number BF953475 (01/2001) and the sequence of Accession number AL110228. The Examiner suggests that the referenced sequences show more than 95% similarity to regions of SEQ ID NO:48 of the instant invention. Thus, the Examiner suggests that these sequences would be expected to selectively hybridize to SEQ ID NO:48.

Further, claims 1-5 have been rejected under 35 U.S.C. 102(a) as being anticipated by the sequence of Accession number AB040959. The Examiner suggests that the referenced sequence has 96% identity to a polynucleotide encoding polypeptide SEQ ID NO:151.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended part (c) of claim 1 in accordance with teachings at pages 13 through 15 of the specification to state that the nucleic acid molecule hybridizes under stringent conditions to a nucleic acid molecule of part (a) or part (b). Further, stringent hybridization conditions are defined specifically in the claim as conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours. Sequences of Accession number BF953475 (01/2001) and Accession number AL110228 would not hybridize under these stringent conditions and therefore do not

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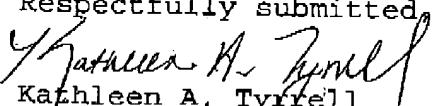
meet the limitations of the claims as amended and thus cannot anticipate the claims as amended.

Further, Applicants have amended claim 1 to delete part (d) thus mooting the rejection over teachings of Accession number AB040959 with respect to percent identity.

Withdrawal of these rejections under 35 U.S.C. § 102(a) is therefore respectfully requested.

VIII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Reg. No. 38,350

Date: August 19, 2004

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Marlton, New Jersey 08053
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BLAST 2 sequences

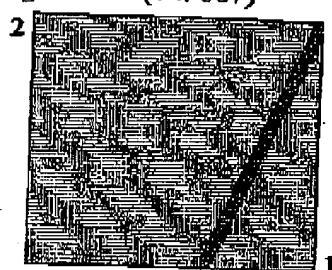
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BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.3 [Apr-24-2002]

Match: 1 Mismatch: -2 gap open: 5 gap extension: 2
x_dropoff: 50 expect: 10,000 wordsize: 11 Filter

Sequence 1 lcl|1_DEX0312_48 Length 1677 (1-1677)

Sequence 2 lcl|2_DEX0312_47 Length 667 (1..667)



NOTE: The statistics (bitscore and expect value) is calculated based on the size of our database.

NOTE: If protein translation is reversed, please repeat the search with reverse strand of the query sequence.

Score = 1238 bits (644), Expect = 0.0
Identities = 646/647 (99%)
Strand = Plus / Plus

Query: 1031 ccataaccctgcctcatcccgatctgtgcagatgaaagagagggagggagaggaaag 1090
Sbjct: 21 ccataaccctgcctcatcccgatctgtgcagatgaaagagagagggagggaaag 80

Query: 1D9I agagagatgtttgggtgtatggccagaggccaccaggctggatccatgaagaat 1150
Sbjct: 81 agagagatgtttgggtgtatggccagaggccaccaggctggatccatgaagaat 140

Query: 1151 ctgggtgagagggtttaaagtcataaaactgagatccagttgcacaggtggctgcatagtt 1210
Sbjct: 141 ctgggtgagagggtttaaagtcataaaactgagatccagttgcacaggtggctgcatagtt 200

Query: 1211 gccaacagtgtaatgtgtcacctttgatctcatcagaatctcaggctggtgccacc 1270
Sbjct: 201 gccaacagtgtaatgtgtcacctttgatctcatcagaatctcaggctggtgccacc 260

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08/19/04 16:44 FAX 856 810 1454 LICATA & TYRELL

Aug 19 2004 11:51AM dialexus, Inc.

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Query: 1391 ctatcattacatagtagtataataataatattagagagatacacagaaaatataatagag 1450
Sbjct: 381 ctatcattacatagtagtataataataatattagagagatacacagaaaatataatagag 440

Query: 1451 aagataaacatgtttctctataaaaaaaaaacagctgcctctgcatacgatcttaacaa 1510
Sbjct: 441 aagataaacatgtttctctataaaaaaaaaacagctgcctctgcatacgatcttaacaa 500

Query: 1511 ctcagcaactctcgcagaaaaagagcacaaaaacgggagaaacaagaaacaaacgggagaca 1570
Sbjct: 501 ctcagcaactctcgcagaaaaagagcacaaaaacgggagaaacaagaaacaaacgggagaca 560

Query: 1571 agactagagaaaacacaggacagcggacaaaaccacgtgagggagcaacaccagaggggc 1630
Sbjct: 561 agactagagaaaacacaggacagcggacaaaaccacgtgagggagcaacaccagaggggc 620

Query: 1631 gaaccacattaccccacacacgtgaaaaagcgagaccagggggaga 1677
Sbjct: 621 gaaccacattaccccacacacgtgaaaaagcgagaccagggggaga 667

Score = 41.1 bits (21), Expect = 0.67
Identities = 40/47 (85%), Gaps = 1/47 (2%)
Strand = Plus / Minus

Query: 1089 agagagagatgtttgggtgtatggccaa-gaggccaccaggctg 1134
Sbjct: 291 agacagacatgtctgcagtgtatggccagggtggccaccaggctg 245

CPU time: 0.01 user secs. 0.00 sys. secs 0.01 total secs.

Lambda K H
1.33 0.621 1.12

Gapped
Lambda K H
1.33 0.621 1.12

Matrix: blastn matrix:1 -2
Gap Penalties: Existence: 5, Extension: 2
Number of Hits to DB: 44
Number of Sequences: 0
Number of extensions: 44
Number of successful extensions: 44
Number of sequences better than 10.0: 1
length of query: 667
length of database: 2,385,885,539
effective HSP length: 24
effective length of query: 643
effective length of database: 2,385,885,515
effective search space: 1534124386145
effective search space used: 1534124386145
T: 0
A: 30
X1: 6 (11.5 bits)
K2: 26 (50.0 bits)
S1: 12 (23.8 bits)

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Aug 19 2004 11:51AM diaDexus, Inc.

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52: 19 (37.2 bits)

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PAGE 19/22 * RCVD AT 8/19/2004 4:43:08 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/6 * DNIS:8729306 * CSID:856 810 1454 * DURATION (mm:ss):05:44

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BLAST 2 sequences

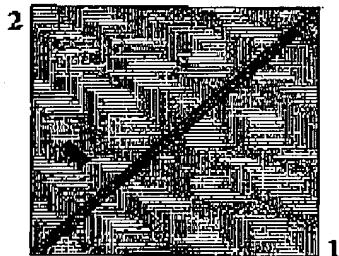
新編增補古今圖書集成

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.3 [Apr-24-2002]

Match: 1 Mismatch: -2 gap open: 5 gap extension: 2
x dropoff: 50 expect: 10.000 wordsize: 11 Filter

Sequence 1 lcl|DEX0155_40 Length 667 (1 .. 667)

Sequence 2 lcl|DEX0312_47 Length 667(1 .. 667)



NOTE: The statistics (bitscore and expect value) is calculated based on the size of nr database.

NOTE: If protein translation is reversed, please repeat the search with reverse strand of the query sequence.

Score = 1283 bits (667), Expect = 0.0

Identities = 667/667 (100%)

Strand = Plus / Plus

Query: 1 gcgtggtcgcccggaggccataaccctgcctcatcccaagatctgtgcagatgaaag 60
||||||| ||||| ||||| ||||| ||||| |||||
Sbjct: 1 gcgtgttcgcggcccgaggccataaccctgcctcatcccaacatctgtgcagatgaaag 60

Query: 61 agagggagggagaggaaagagagagatgcttgggtgtatggccagaggccaccag 120
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||
Sbjct: 61 agagggagggagaggaaagagagagatgcttgggtgtatggccagaggccaccag 120

Query: 121 gctggatcccatgaagaatctgggtgagagggtcttaaagtataaactgagatccagt 180
Sbjct: 121 gctggatcccatgaagaatctgggtgagagggtcttaaagtataaactgagatccagt 180

Query: 181 tgccagggtggctgcatagttgcacaaagtgtaatgtgtcacctttatcttcatcagaa 240
Sbjct: 181 tgccagggtggctgcatagttgcacaaagtgtaatgtgtcacctttatcttcatcagaa 240

Query: 241 atctcagccgttgtggccacctggccaaatacactgcagagcatgtctgtctgtctgtctg 300
Sbjct: 241 atctcagccgttgtggccacctggccaaatacactgcagagcatgtctgtctgtctgtctg 300

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Aug 19 2004 11:52AM diaDexus, Inc.

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Query: 361 tgtctccactttcatcctatcattacatagttagtataataataatattagagaga 420
Sbjct: 361 tgtctccactttcatcctatcattacatagttagtataataataatattagagaga 420

Query: 421 tacacagaaaatatataagagaagataaacagtgttctctataaaaaaaaaacagctgccct 480
Sbjct: 421 tacacagaaaatatataagagaagataaacagtgttctctataaaaaaaaaacagctgccct 480

Query: 481 ctctgcatacgcttctaacaactcagcaactctcgagaaaagagcacaaaaacgggagaaa 540
Sbjct: 481 ctctgcatacgcttctaacaactcagcaactctcgagaaaagagcacaaaaacgggagaaa 540

Query: 541 caagaaacaaacgggagacaagacttagagaaaacacaggacagcggacaaaaccacgtga 600
Sbjct: 541 caagaaacaaacgggagacaagacttagagaaaacacaggacagcggacaaaaccacgtga 600

Query: 601 gggagcaacaccagagggcgaaccacattacccacacacgtgaaaaagcgagaccagg 660
Sbjct: 601 gggagcaacaccagagggcgaaccacattacccacacacgtgaaaaagcgagaccagg 660

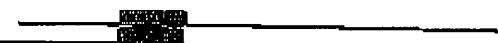
Query: 661 ggggaga 667
Sbjct: 661 ggggaga 667

Score = 41.1 bits (21), Expect = 0.67
Identities = 40/47 (85%), Gaps = 1/47 (2%)
Strand = Plus / Minus



Query: 245 cagcctggtgccacctggccaaatacactgcagagcatgtctgtct 291
Sbjct: 124 cagcctggtgccctc-tggccaaatacaccacaaagcatctctct 79

Score = 41.1 bits (21), Expect = 0.67
Identities = 40/47 (85%), Gaps = 1/47 (2%)
Strand = Plus / Minus



Query: 79 agagagagatgcttgggtgtatggcca-gaggccaccaggctg 124
Sbjct: 291 agacagacatgcctgcagtgtatggccaggtgccaccaggctg 245

CPU time: 0.01 user secs. 0.00 sys. secs 0.01 total secs.

Lambda K H
1.33 0.621 1.12

Gapped
Lambda K H
1.33 0.621 1.12

Matrix: blastn matrix:1 -2
Gap Penalties: Existence: 5, Extension: 2
Number of Hits to DB: 45

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Aug 19 2004 11:53AM diaDexus, Inc.

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Number of Sequences: 0
Number of extensions: 45
Number of successful extensions: 45
Number of sequences better than 10.0: 1
length of query: 667
length of database: 2,385,885,539
effective HSP length: 24
effective length of query: 643
effective length of database: 2,385,885,515
effective search space: 1534124386145
effective search space used: 1534124386145
T: 0
A: 30
X1: 6 (11.5 bits)
X2: 26 (50.0 bits)
S1: 12 (23.8 bits)
S2: 19 (37.2 bits)